



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Supplemental Evidence and Data Request on Nutrition as Prevention for Improved Cancer Outcomes

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Request for Supplemental Evidence and Data Submissions.

SUMMARY: The Agency for Healthcare Research and Quality (AHRQ) is seeking scientific information submissions from the public. Scientific information is being solicited to inform our review on *Nutrition as Prevention for Improved Cancer Outcomes*, which is currently being conducted by the AHRQ's Evidence-based Practice Centers (EPC) Program. Access to published and unpublished pertinent scientific information will improve the quality of this review.

DATES: *Submission Deadline* on or before [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES:

E-mail submissions: epc@ahrq.hhs.gov

Print submissions:

Mailing Address:

Center for Evidence and Practice Improvement

Agency for Healthcare Research and Quality

ATTN: EPC SEADs Coordinator

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FOR FURTHER INFORMATION CONTACT: Jenae Benms, Telephone: 301-427-1496 or

Email: epc@ahrq.hhs.gov.

SUPPLEMENTARY INFORMATION: The Agency for Healthcare Research and Quality has commissioned the Evidence-based Practice Centers (EPC) Program to complete a review of the evidence for *Nutrition as Prevention for Improved Cancer Outcomes*. AHRQ is conducting this technical brief pursuant to Section 902 of the Public Health Service Act, 42 U.S.C. 299a.

The EPC Program is dedicated to identifying as many studies as possible that are relevant to the questions for each of its reviews. In order to do so, we are supplementing the usual manual and electronic database searches of the literature by requesting information from the public (e.g., details of studies conducted). We are looking for studies that report on *Nutrition as Prevention for Improved Cancer Outcomes*, including those that describe adverse events. The entire research protocol is available online at:

<https://effectivehealthcare.ahrq.gov/products/improved-cancer-outcomes/protocol>

This is to notify the public that the EPC Program would find the following information on *Nutrition as Prevention for Improved Cancer Outcomes* helpful:

- A list of completed studies that your organization has sponsored for this indication.

In the list, please *indicate whether results are available on ClinicalTrials.gov along with the ClinicalTrials.gov trial number.*

- *For completed studies that do not have results on ClinicalTrials.gov, a summary, including the following elements: study number, study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, primary and secondary outcomes, baseline characteristics, number of patients screened /eligible /enrolled /lost to follow-up /withdrawn /analyzed, effectiveness/efficacy, and safety results.*
- *A list of ongoing studies that your organization has sponsored for this indication. In the list, please provide the ClinicalTrials.gov trial number or, if the trial is not registered, the protocol for the study including a study number, the study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, and primary and secondary outcomes.*
- *Description of whether the above studies constitute ALL Phase II and above clinical trials sponsored by your organization for this indication and an index outlining the relevant information in each submitted file.*

Your contribution is very beneficial to the Program. Materials submitted must be publicly available or able to be made public. Materials that are considered confidential; marketing materials; study types not included in the review; or information on indications not included in the review cannot be used by the EPC Program. This is a voluntary request for information, and all costs for complying with this request must be borne by the submitter.

The draft of this review will be posted on AHRQ's EPC Program website and available for public comment for a period of 4 weeks. If you would like to be notified when the draft is posted, please sign up for the e-mail list at: <https://www.effectivehealthcare.ahrq.gov/email-updates>.

The systematic review will answer the following questions. This information is provided as background. AHRQ is not requesting that the public provide answers to these questions.

Key Questions (KQ)

KQ 1: In adults diagnosed with cancer who have or are at risk for cancer-associated malnutrition, what is the effect of nutritional interventions *prior to* cancer treatment in preventing negative treatment outcomes such as effects on dose tolerance, hospital utilizations, adverse events and survival?

- a. Do the effects of nutritional interventions on preventing the negative outcomes associated with cancer treatment vary by cancer type, treatment type (chemotherapy, radiation, surgery) and stage of disease?
- b. Do the effects of nutritional interventions vary across the lifespan (e.g., adults aged ≥ 65 years vs. < 65 years)?
- c. KQ1c: Compared to adults without muscle wasting, do nutritional interventions prevent the negative outcomes associated with cancer treatment in adults with muscle wasting?
- d. KQ1d: Do the effects of nutritional interventions on preventing the negative outcomes associated with cancer treatment vary across special populations (e.g., individuals with multiple comorbid conditions)?

KQ 2: In adults diagnosed with cancer who have or are at risk for cancer-associated malnutrition, what is the effect of nutritional interventions *during* cancer treatment in preventing

negative treatment outcomes such as effects on dose tolerance, hospital utilizations, adverse events and survival?

- a. Do the effects of nutritional interventions on preventing the negative outcomes associated with cancer treatment vary by cancer type, treatment type (chemotherapy, radiation, surgery) and stage of disease?
- b. Do the effects of nutritional interventions vary across the lifespan (e.g., adults aged ≥ 65 years vs. < 65 years)?
- c. Compared to adults without muscle wasting, do nutritional interventions prevent the negative outcomes associated with cancer treatment in adults with muscle wasting?
- d. Do the effects of nutritional interventions on preventing the negative outcomes associated with cancer treatment vary across special populations (e.g., individuals with multiple comorbid conditions)?

KQ 3: In adults diagnosed with cancer who have or are at risk for cancer-associated malnutrition, what is the effect of nutritional interventions *prior to* or *during* cancer treatment on associated symptoms such as fatigue, nausea and vomiting, appetite, physical and functional status (e.g., frailty), and quality of life?

- a. Do the effects of nutritional interventions on symptoms associated with cancer treatment vary by cancer type, treatment type (chemotherapy, radiation, surgery) and stage of disease?
- b. Do the effects of nutritional interventions vary across the lifespan (e.g., adults aged ≥ 65 years vs. < 65 years)?
- c. Compared to adults without muscle wasting, do nutritional interventions differentially effect symptoms associated with cancer treatment in adults with muscle wasting?
- d. Do the effects of nutritional interventions on symptoms associated with cancer treatment vary across special populations (e.g., individuals with multiple comorbid conditions)?

KQ 4: In adults with cancer who are overweight or obese, what is the effect of nutritional interventions intended for weight loss *prior to* or *during* cancer treatment in preventing negative treatment outcomes such as effects on dose, hospital utilizations, adverse events and survival?

Contextual Question (CQ):

CQ 1: What evidence is available on the cost-effectiveness of nutritional interventions for preventing negative outcomes associated with cancer treatment?

PICOTS (Population, Intervention, Comparator, Outcome, Timing, Setting)

PICOTS	KQ1: Pre-Treatment Nutritional Interventions (PNIs)	KQ2: Nutritional Interventions During Treatment (NIDTs)	KQ3: Pre- or During Treatment Nutritional Interventions (NIs) and Patient-Centered Outcomes	KQ4: Weight Loss in Overweight/Obese Adults with Cancer
Population	Adults diagnosed with cancer at or after age 18 who have or are at risk for cancer-associated malnutrition Subgroups: <ul style="list-style-type: none"> • Cancer and treatment characteristics (cancer type, treatment type (systemic therapy, radiation, surgery), stage of disease) • Adults ≥ 65y vs younger • Muscle wasting (e.g., sarcopenia, cachexia, pre-cachexia) vs. no muscle wasting • Special populations (individuals with multiple co-morbid conditions) 			Overweight (BMI 25- <30)/obese (BMI ≥ 30) adults ≥ 18 y of age diagnosed with cancer
Interventions	Nutritional interventions under the supervision of a nutrition professional (e.g., dietician, nutritionist, or other licensed clinicians) <ul style="list-style-type: none"> • Diet or nutrition therapy (via oral or enteral (e.g. nasogastric, gastrostomy, jejunostomy) feeding <ul style="list-style-type: none"> ○ Special diets (e.g., fasting (intermittent or short-term), calorie restriction, ketogenic, 			Nutritional Interventions intended for weight loss (includes both PNIs and NIDTs)

PICOTS	KQ1: Pre-Treatment Nutritional Interventions (PNIs)	KQ2: Nutritional Interventions During Treatment (NIDTs)	KQ3: Pre- or During Treatment Nutritional Interventions (NIs) and Patient-Centered Outcomes	KQ4: Weight Loss in Overweight/Obese Adults with Cancer
	Mediterranean diet, high calorie, high protein) ○ Supplements <ul style="list-style-type: none"> • Total parenteral therapy • Nutritional counseling • Combined nutritional interventions (e.g., nutritional counseling with nutrition therapy) 			
Comparators	Standard of care vs PNIs or PNIs vs PNIs	Standard of care vs NIDTs, NIDT vs NIDT or PNIs vs. NIDTs	Standard of care vs PNIs or NIDTs, NIDTs vs. NIDTs, PNIs vs. PNIs, PNIs vs NIDTs	Standard of care vs PNIs or NIDTs, NIDTs vs. NIDTs, PNIs vs. PNIs, PNIs vs NIDTs
Outcomes	Intermediate Outcomes BMI, Body composition, Weight (loss, gain) Final Outcomes Cancer treatment tolerance: treatment interruptions, reductions, or delays Hospital utilizations: ER visits, Admissions, Length of stay Adverse events <ul style="list-style-type: none"> • Chemotherapy /radiation therapy limiting toxicity • Post-op complication • NI-related AEs • Unintended harms Survival Nutritional status Malnutrition (underweight, wasting, overweight)			Intermediate Outcomes BMI, Body composition, Weight (loss, gain) Final Outcomes Cancer treatment tolerance: treatment interruptions, reductions, or delays Hospital utilizations: ER visits Admissions, Length of stay Adverse events <ul style="list-style-type: none"> • Chemotherapy/radiation therapy limiting toxicity • Post-op complication • NI-related AEs • Unintended harms Survival Nutritional Status Malnutrition (underweight, wasting, overweight)
Timing	Nutritional interventions delivered pre- cancer treatment (KQ1, KQ3, KQ4) and during cancer treatment (KQ2, KQ3, KQ4)			

PICOTS	KQ1: Pre-Treatment Nutritional Interventions (PNIs)	KQ2: Nutritional Interventions During Treatment (NIDTs)	KQ3: Pre- or During Treatment Nutritional Interventions (NIs) and Patient-Centered Outcomes	KQ4: Weight Loss in Overweight/Obese Adults with Cancer
Setting	Outpatient Oncology Care, Ambulatory Care, Cancer Treatment Centers, inpatient, home-based, hospice, telemedicine			

Abbreviations: KQ=key question; BMI=body mass index; ER=emergency room; PICOTS=population, intervention, comparator, outcomes, timing, setting; RCT=randomized controlled trial; NRCT=non-randomized controlled trial

Dated: October 22, 2021.

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